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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,173	12/12/2000	Edward D. Ball	MXI-026DVCN2	5414

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LAHIVE & COCKFIELD  
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BOSTON, MA 02109

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

9

DATE MAILED: 02/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/735,173

Applicant(s)

BALL ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 25-37 is/are pending in the application.
- 4a) Of the above claim(s) 30-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. The amendment filed 11/29/2002 (paper no 8) is acknowledged and entered into the record. No new claims have been added or canceled.

2. Claims 25-37 are currently pending, claims 30-37 are withdrawn from consideration. Therefore, claims 25-29 are examined on the record.

***Claim Rejections Withdrawn- 35 USC § 112, 2<sup>nd</sup> paragraph***

3. The rejection of claim 28 under 35 USC 112, 2<sup>nd</sup> paragraph as being indefinite is withdrawn in view of the amendments to the claim.

***Claim Rejections Withdrawn- 35 USC § 112, 1<sup>st</sup> paragraph***

4. The rejection of claim 28 under 35 USC 112, 1<sup>st</sup> paragraph as lacking proper written description is withdrawn in view of the amendment to the claim.

***Claim Rejections Withdrawn- 35 USC § 102***

5. The rejection of claims 25 and 29 under 35 USC 102 (a) as being anticipated by Shin *et al* is withdrawn, in view of the persuasive arguments presented by the applicant.

***Claim Rejections Withdrawn- 35 USC § 103***

6. The rejection of claims 25-29 under 35 USC 103(a) as being obvious over Shin *et al* in view of Cuttitta *et al* is withdrawn in view of the persuasive arguments presented by the applicant.

***Claim Rejections Maintained- 35 USC § 112, 1<sup>st</sup> paragraph***

7. The rejection of claims 25-29 under 35 USC 112, 1<sup>st</sup> paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the instant application is fully enabled and that some experimentation is acceptable

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because the instant specification has provided ample guidance in the form of construction and testing of the instant bispecific molecule. Applicant's arguments have been carefully considered but are not found persuasive for the following reasons. The claims of the instant specification are drawn to any and all bispecific molecules that comprises an autocrine growth factor and an antibody or antigen binding fragment wherein the molecule does not bind in the same binding pocket as that of an endogenous immunoglobulin. Although the instant specification does provide guidance in terms of constructing and testing of a specific bispecific molecule namely, bombesin coupled to mAb22, it does not provided any guidance for any and all bi-specific molecules. Although it is routine for one of skill in the art to conjugate any growth factor to any antibody or antigen binding fragment, it is not routine experimentation to find any antibody that is able to bind to an Fc receptor at an epitope that is different and distinct from that of an endogenous immunoglobulin. Such determination would require one of skill in the art to perform undue experimentation to practice and make the invention commensurate in scope to the claims. Currently, the specification of the instant invention has only enabled the conjugation of autocrine growth factors to one specific antibody or antigen binding fragment, namely mAb22.

***Claim Rejections Maintained- Double Patenting***

8. The rejection of claims 25-29 under judicially created doctrine of obviousness type double patenting is maintained for the reasons of record. Applicant states that a terminal disclaimer will be filed upon notification of allowable subject matter. ~~Also~~ C.Y.

***Conclusion***

9. No claim is allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Christopher Yaen

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February 5, 2003

  
ALI R. SALIMI  
PRIMARY EXAMINER